REMARKS

Initially, Applicant would like to thank the Examiner for the indication of allowable subject matter. Specifically, the Examiner has stated that claims 19-31 patentably define over the prior art.

Election of Species/Restriction

The Examiner has made the election of species requirement final and has withdrawn claims 1-11, 14 and 15 from further consideration. For the reasons previously articulated, Applicant continues to traverse this requirement in general and with respect to claims 14 and 15 as presented herein.

The Examiner further states that Applicant's previous inclusion of claims 14 and 15 with the election of Species I, related to FIGS. 3 and 4 is "not accepted". The Examiner asserts, "claims 14 and 15 are directed to Figure 7, which has no separate passageway for drug delivery." Applicant respectfully traverses the withdrawal and the argument supporting that withdrawal.

Claims 14 and 15 are presented as follows:

14. The medical catheter device of claim 13, wherein the distribution device attached near the distal end of the tubular body comprises a chemically modified material.

15. The medical catheter device of claim 13, wherein the distribution device attached near the distal end of the tubular body comprises a sponge-like saturated material.

There is absolutely no language present in either claim that would limit or direct either claim to a device that "has no separate passageway for drug delivery;" conversely, there is no language in either claim that would preclude incorporation into an embodiment that included a "separate passageway for drug delivery." The Examiner is respectfully reminded that it is the language of the

claims that must be examined. As such, the withdrawal of the claims is without merit and must be withdrawn.

The Examiner has indicated that paragraph 38 of the published application provides support for this conclusion. Applicant again states that the language of the claims is clear and unambiguous and is in no way limited to a species defined by not having a "separate passageway for drug delivery." Paragraph 38 indicates that "FIG. 7 presents an alternate embodiment. . . with no separate passageway." Thus, this is the distinction relied upon by the Examiner and may *arguendo* set apart a species distinction between an embodiment with a separate passageway and one without. That, however, is the extent of what may even arguably be drawn. Paragraph 38 continues to state that distribution device 48

> "can be impregnated with the vasodilating agents prior to the catheter device 40b being inserted into the patient. The design parameters of the distribution device 48 material, such as porosity of the material and the relative surface tensions of the distribution device 48 material and the vasodilating agents, will determine the rate of dissipation of the vasodilating agents from the distribution device 48. The distribution device 48 can comprise a sponge-like substance that can be saturated or impregnated by the vasodilating agents. Vasodilators can also be applied by chemically binding to or modifying the distribution device 48 material."

Distribution device 48 is an element common to FIGS. 3 and 4 *and 7*. There is no legal or procedural basis upon which the Examiner may properly limit the understanding of an element based solely upon where supporting material in the specification happens to be presented. More specifically, because various embodiments of distribution device 48 are explained in the context of FIG. 7 in no way limits that understanding of the same distribution device 48 in the context of other embodiments and other figures.

As distribution device 48 is an element common to multiple embodiments, multiple species (as mandated by the Examiner) and multiple Figures, that term is given its broadest reasonable interpretation consistent with the specification and cannot be limited "by association." To the extent the Examiner may be relying upon the wholly inappropriate and subjective textual descriptions created by the previous Examiner in an earlier Office Action, such reliance would be improper and unsupportable under the law and the rules of practice (please see Applicant's previous responses). The species requirement is based upon the Figures and may not include arbitrarily incorporated elements pulled from the specification on an *ad hoc* basis. This clearly illustrates why such subjective grouping and description generated by an Examiner outside of what is defined by Applicant in their own application and claims is inappropriate and problematic.

The Examiner has also rejected claims 12, 13, 16, 17, and 18 under 35 USC 112, first paragraph as failing to comply with the written description requirement. According to the Examiner, it "is unclear how the distributor 48 of Figures 3 and 4 are operable to disperse a vasodilating agent since it doesn't have any orifices. It just looks like a balloon catheter." With all due respect, such a rejection is without merit and must be withdrawn. Elements may be illustrated schematically and in following the above reasoning, multiple versions/embodiments are schematically illustrated precisely to prevent an inappropriate limitation from being drawn from an over reliance on a Figure (or what an element subjectively "looks like") without reference to the specification.

Distributor 48 is shown in various embodiments and described throughout the specification. An understanding of what distributor 48 is and how it may work it not limited solely to Figures 3 and 4 and the portion of the specification specifically directed to a description of those Figures.

To understand how distributor 48 may operate to dispense a vasodilating agent, the Examiner need look no further than the paragraph [0038] improperly relied upon to withdraw claims 14 and 15.

> The design parameters of the distribution device 48 material, such as porosity of the material and the relative surface tensions of the distribution device 48 material and the vasodilating agents, will determine the rate of dissipation of the vasodilating agents from the distribution device 48. **The distribution device 48 can comprise a sponge-like substance that can be saturated or impregnated by the vasodilating agents.** Vasodilators can also be applied by chemically binding to or modifying the distribution device 48 material." (Emphasis added)

Thus, by connecting a "sponge like" distribution device to a separate passageway for delivery of the agent will "saturate" and hence distribute the agent. This provides a clear understanding to anyone of skill in the art how the distributor would operate in one embodiment and how the written description requirement is satisfied. Furthermore, this clearly illustrates why the entire specification and all drawings must be considered in its entirety without limitation to subsections of the specification based upon a subsequently imposed election of species requirement. Thus, claims 14 and 15 must be considered and examined and the rejection under section 112 must be withdrawn, as it is unsupportable.

The Examiner has rejected claims 12, 13, 16, 17 and 18 under 35 USC 102(b) over Machold et al. ("Machold"). Applicant respectfully traverses this rejection. As the Examiner is well aware, in order to establish a rejection under section 102, each and every element of the claims must be described within the reference. Contrary to the Examiner's assertion, Machold does not teach a "means of dispersing at least one vasodilating agent." As such, the rejection is unsupportable under section 102 and must be withdrawn.

Claim 12 includes language consistent with 35 USC 112, paragraph 6 and as such, the claim language must be read to include the structure(s) described within the specification and equivalents thereof. The claimed device provides a

catheter for delivery of an electrical lead and the above referenced means for dispersing. The means for dispersing include multiple embodiments, one of which is the above-described sponge-like member. No embodiment is specifically taught that includes a dual layer inflatable member having a porous exterior layer, wherein inflation of an inner member disperses an agent through the likewise inflated but porous exterior layer.

Furthermore, the claim includes distributing the agent adjacent the distal end of the lumen. The present invention utilizes the vasodilating agent to permit an electrical lead to be advanced into a vein/artery after dilation. The Machold device is utilized for angioplasty and by definition, is advanced to the desired position before inflation and release of the agent. As such, the reference does not teach the means for dispersing as claimed.

Applicant respectfully asserts that the claims are allowable and requests notice of the same. If any issues remain, the Examiner is urged to telephone the undersigned to expedite prosecution.

Respectfully submitted,

Date: 2/15/05

Daniel G. Chapik
Reg. 43,424
Telephone: (763) 514-3066
Customer No. 27581